Experience with End to End Solution

NIH Standards & Modularity of BCIs and Neuroprostheses

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Some Questions…

- Modularity– Advantages? How much?
- (S)tandardization or (s)tandardization? How much can this aid us?
- In light of commercial potential, why is standardization necessary?
- The regulatory process: navigating the process in light of technical innovation and challenges
- Other…

Disclaimer

- I do not work with BCI per se – unless you consider the EMG signals recorded from the periphery to control electrically stimulated paralyzed muscles a “BCI interface”
- But… our experience in designing a three generations of implantable systems from the ground up and into human clinicals will hopefully have relevance to the BCI community

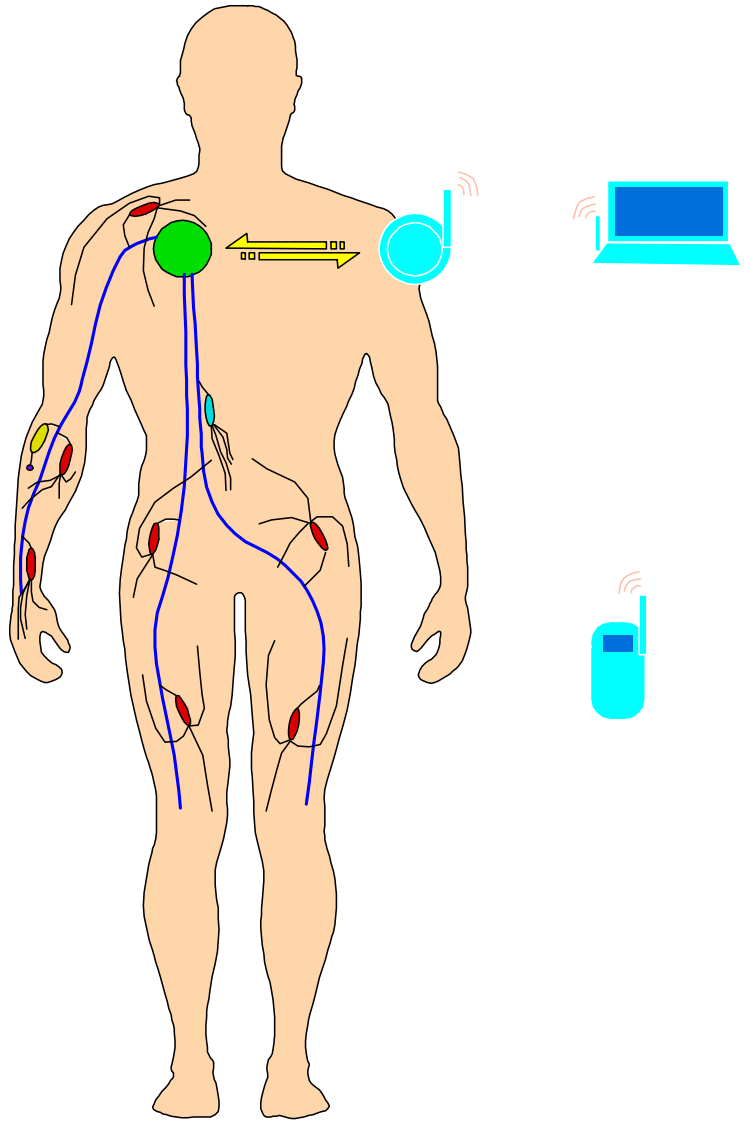
Use Characteristics

- PNS manifestations
- Throughout body
- Highly heterogeneous injuries (need to “customize” applications)
- Often desire to sense activity and stimulate activity or block activity from different regions of the body
- Users desire availability 24/7
- NOTHING external

=> Adaptive fully implantable, programmable neuromodulation technology

Networked Neuroprosthesis

- Applicable to multi-system dysfunction
- Fully implantable
- No external components during functional use
- Modular
- Scalable
- Upgradeable components
- Externally programmable



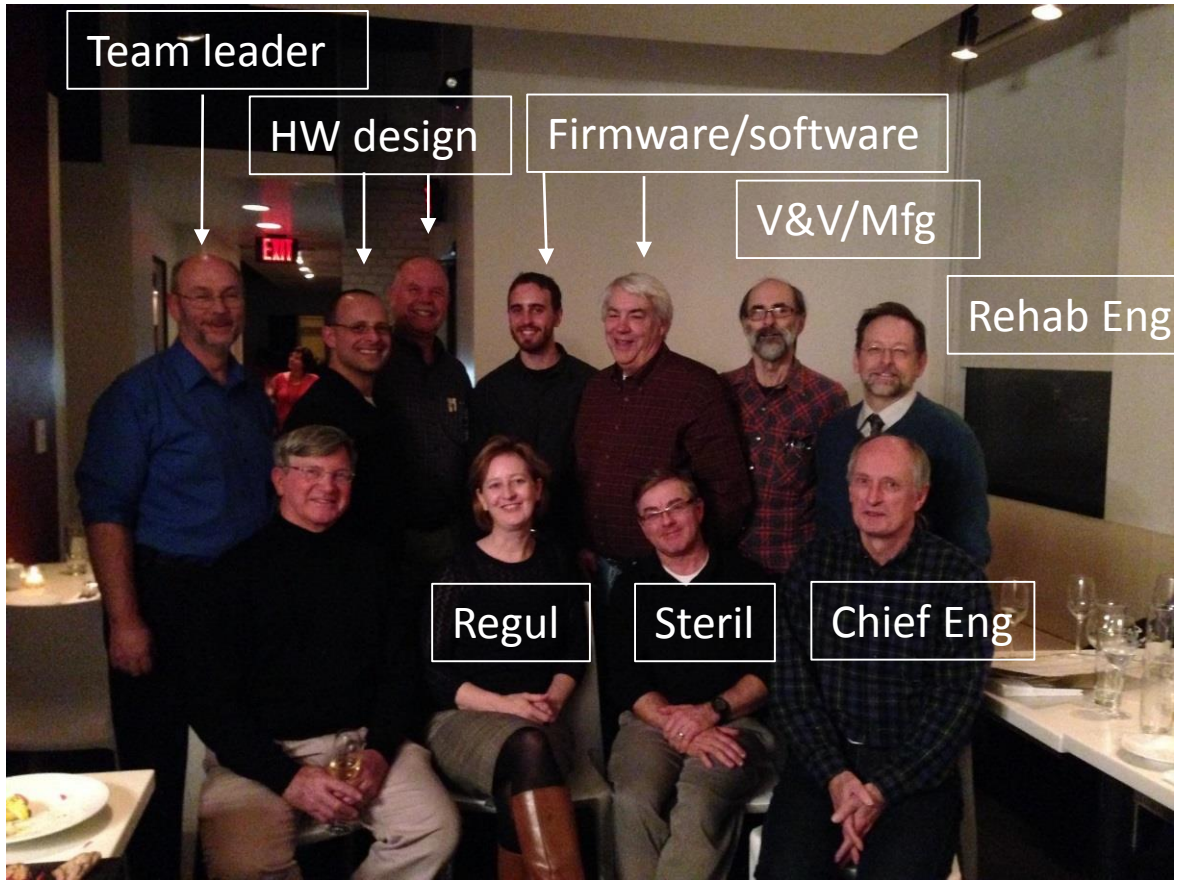
NNP Design Team

Kevin Kilgore

Brian Smith

Mike Keith
Hand/Ortho

Jim Buckett
EE/BME



…and a host of subcontractors

High Level Design Principles

- No external components during functional use
- Modularity, Flexibility and Configurability of System Components
- Ability to modify or upgrade system without complete implant removal
- Surgical installation with limited incisions
- System architecture optimized for patient safety and maximum functionality

Design Concept

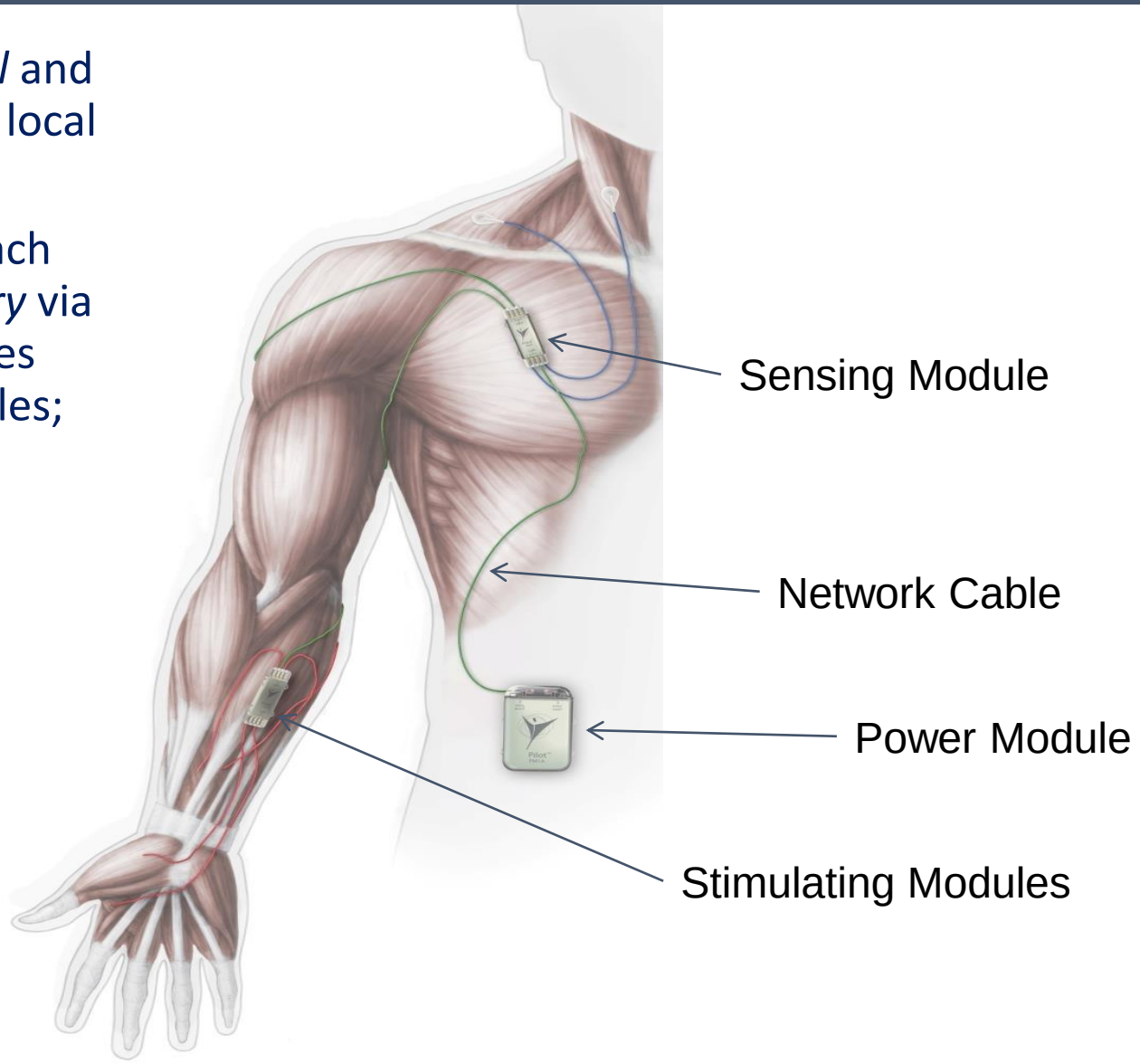
- Platform Technology that would enable multiple system implementation
- Enable future implementation (without fully designing entire implantable system
- Design innovations account for regulatory approval (limit “new” biomaterials)
- Design internally with transdisciplinary team – use subcontractors for specialized fabrication processes
- Enable fabrication by manufacturer of record
- Design controls throughout
- Expand “use cases” over time

AS TIME MOVED ON:

- Provide as tool to the research community and industry for neuromodulation clinical exploration and studies

The Networked Neuroprosthesis (NNP) Concept

- Stimulating and Sensing Modules are *small* and *distributed* remotely throughout the body, local to their target area;
- The Power Module distributes power to each module from a *central rechargeable battery* via the network cable; a *network cable* provides the communication link between all modules;
- No external hardware (except for battery recharging and programming)
- Optional external control inputs
- Design flexibility for new functionality



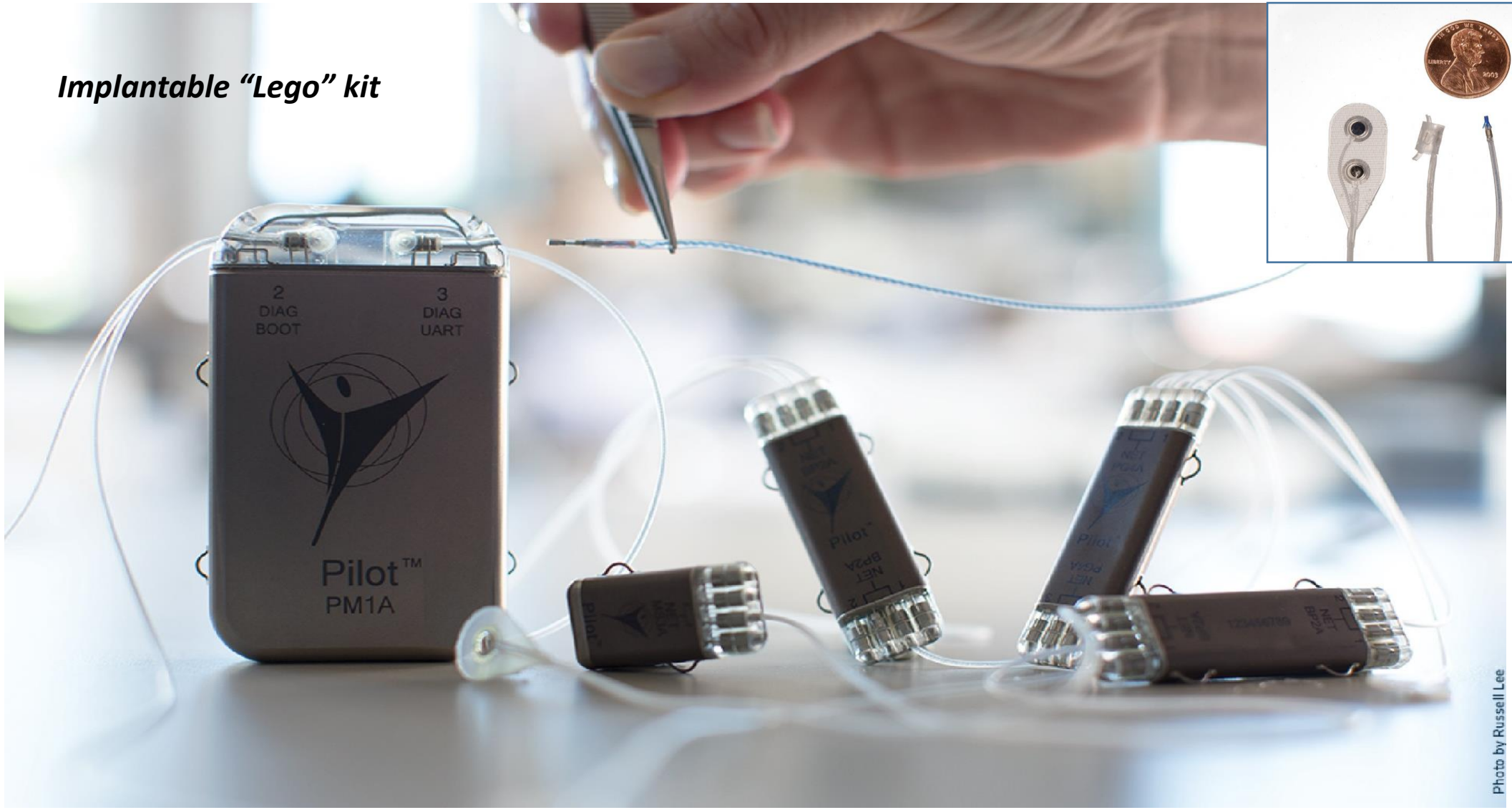
Why Modular

ANSWER:

- For typical (non-modular) systems, implants are designed for one specific use-case making it difficult to adapt to other applications.
- Prohibitive in cost and time to develop new hardware for each new application
- Costly and slow manufacturing procedures
  - ➔ Designed for very small volumes
  - ➔ Manufacturing procedures becoming outdated
- Severely limits new applications and progress in the field and delays introduction of new technology and methods to the end user

Networked Neuroprosthesis

Implantable "Lego" kit



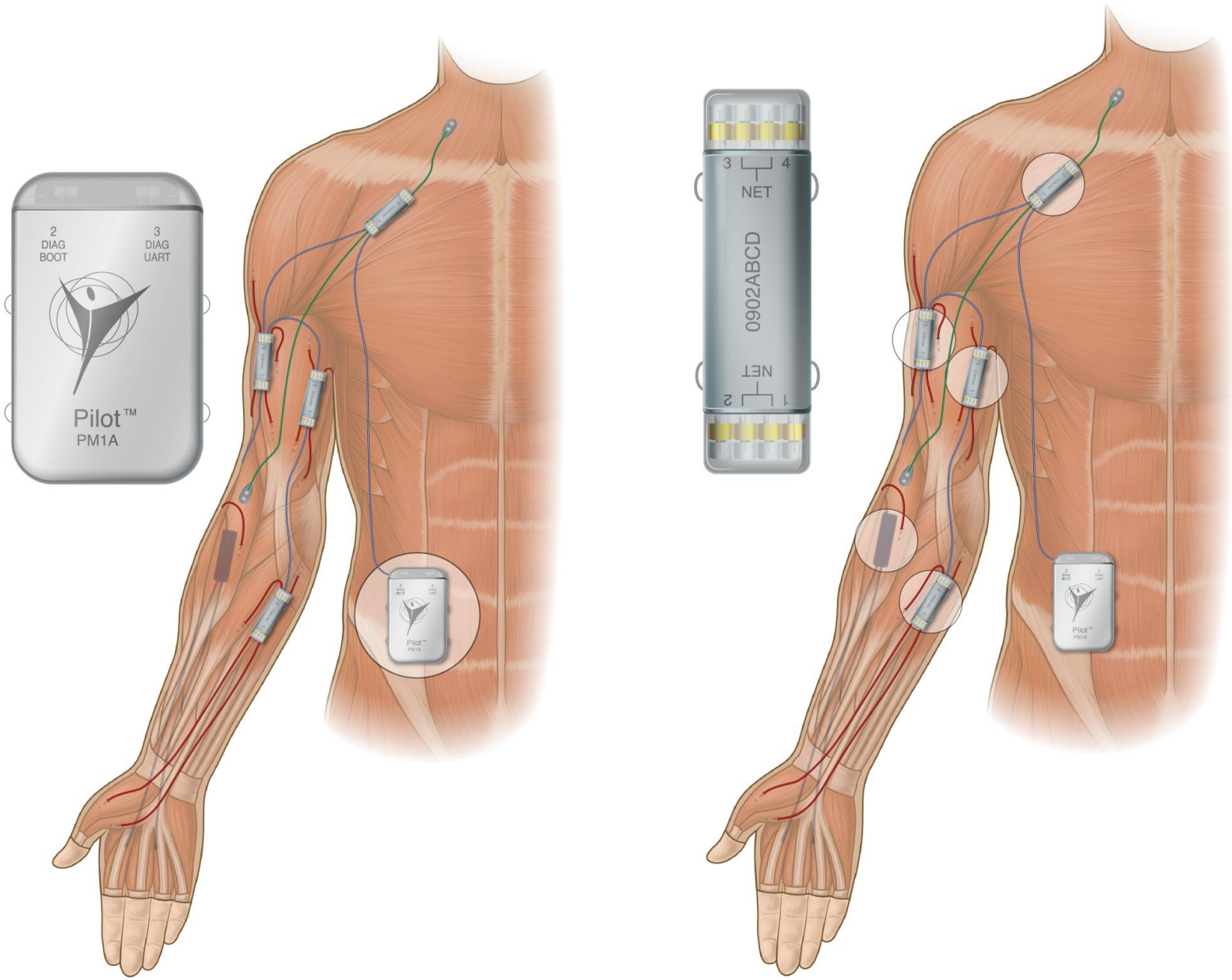
Where in the NNP design have we introduced modularity and standardization

Modularity

- Overall modular concept – allows distributed clinical implementation
- Internal modular design of remote modules allows new circuits (new functions) to be implemented without having to design entire new module (avoid mechanical design issues)

Standardization

- Mechanical (enclosure) design of packaging
- Interconnections between modules
- Connectors on leads/electrodes
- Communications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BOOT
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NET
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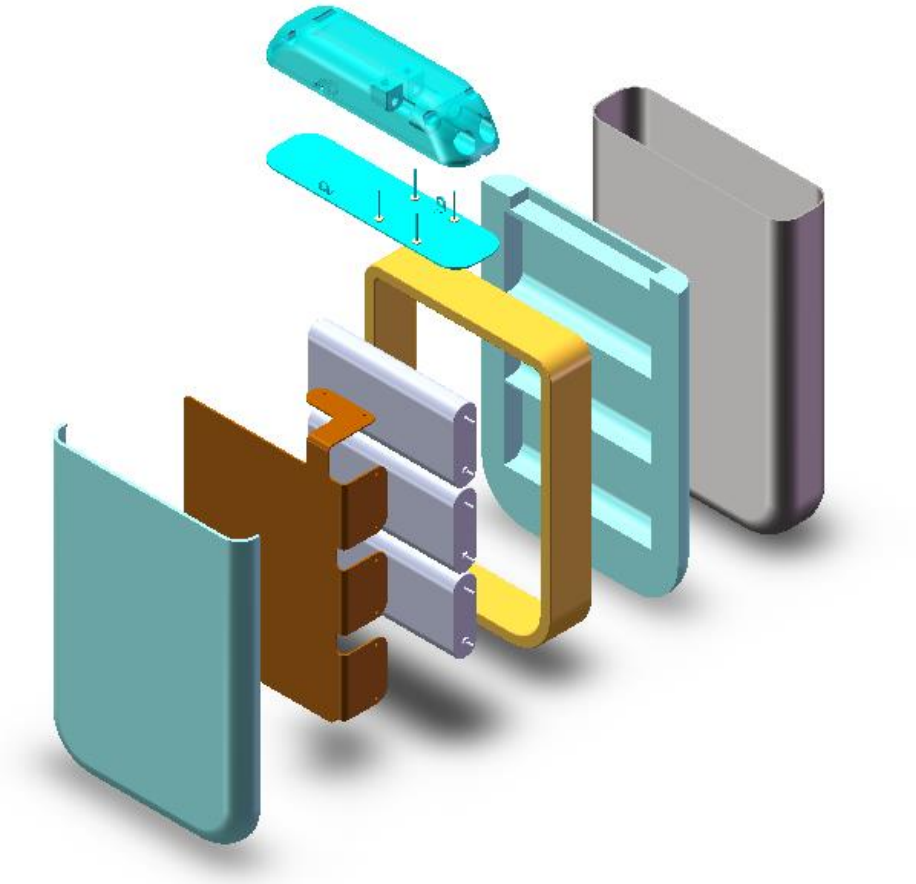
Pilot™
PM1A

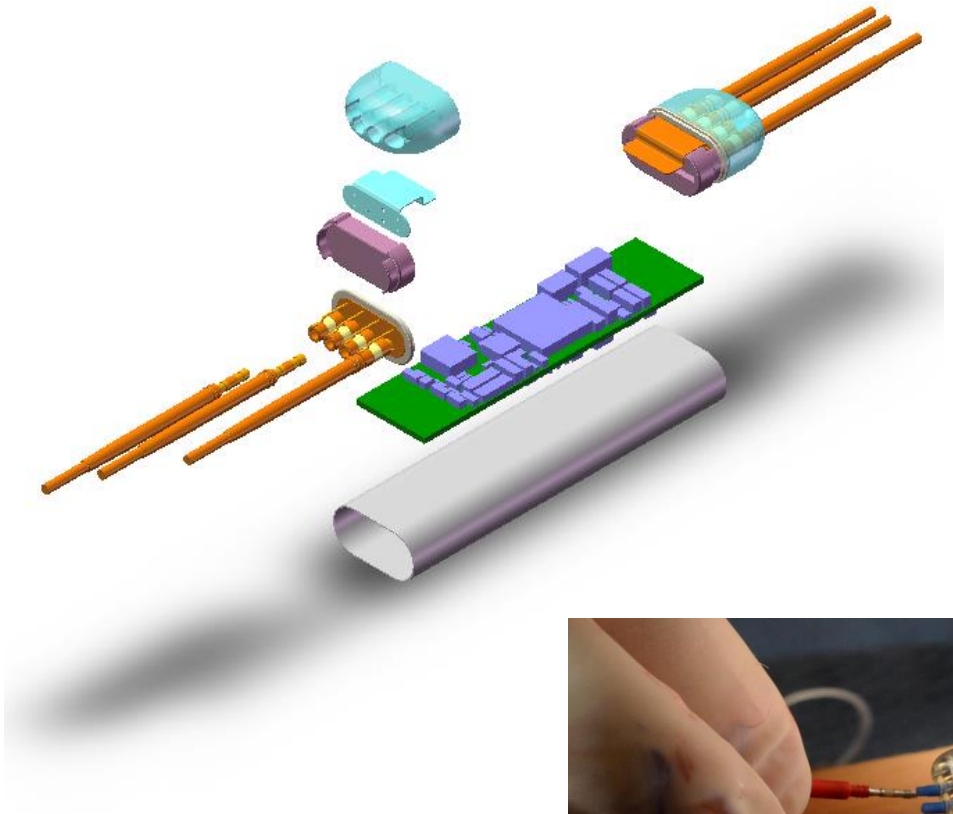
Power Module

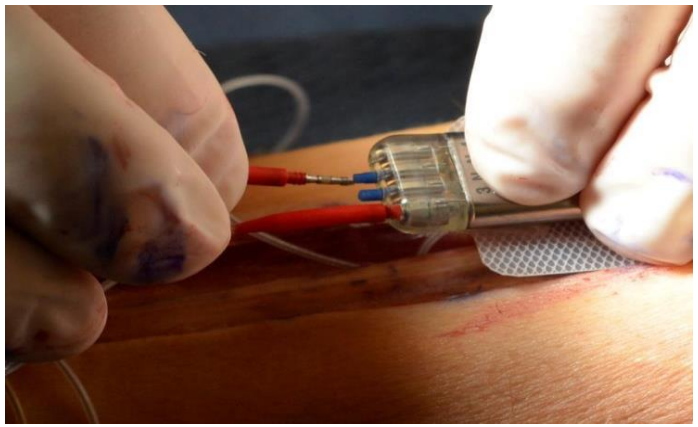
- Sized for torso: ~2”x3”
- Rechargeable Li-ion batteries
- Recharging Circuitry
- Wireless transcutaneous link
- Network Maintenance hardware
- Processing capabilities



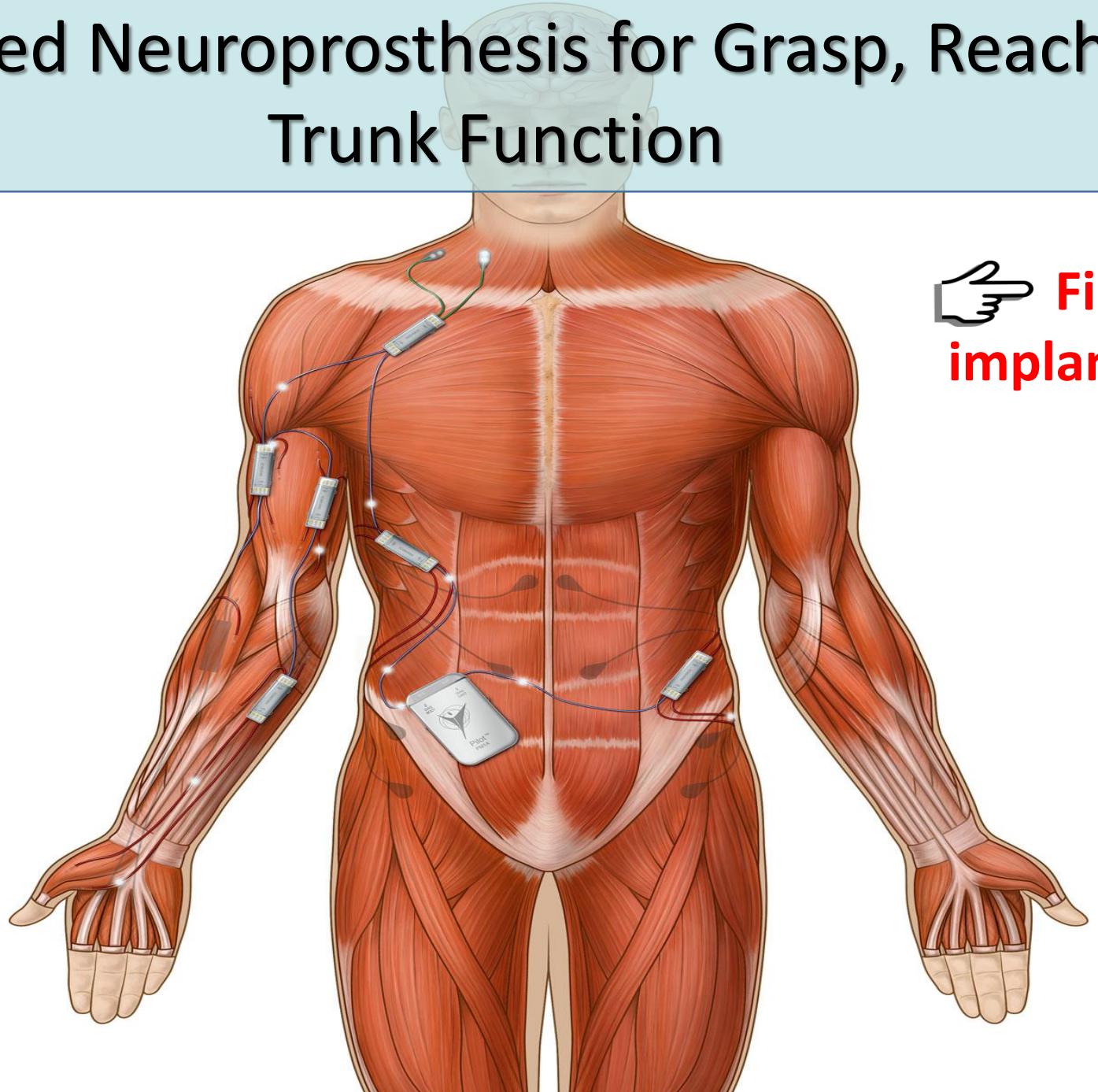
Remote Module Physical Design

- Remote Modules
  - All non power modules
- Sized for limbs:
  - ~0.4”x0.25”x2+”
- Open Architecture
  - Facilitate future design
- Network Cable
  - Daisy Chain

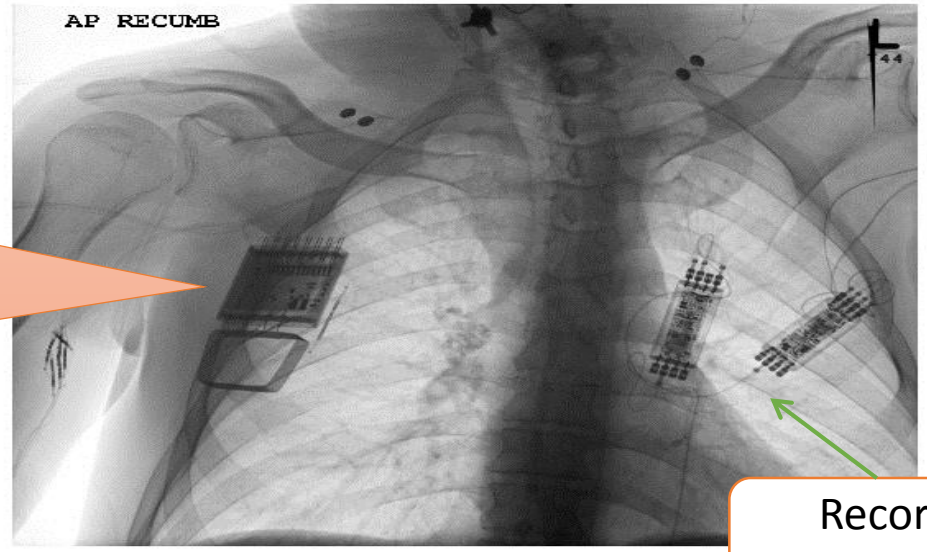




Networked Neuroprosthesis for Grasp, Reach, and Trunk Function

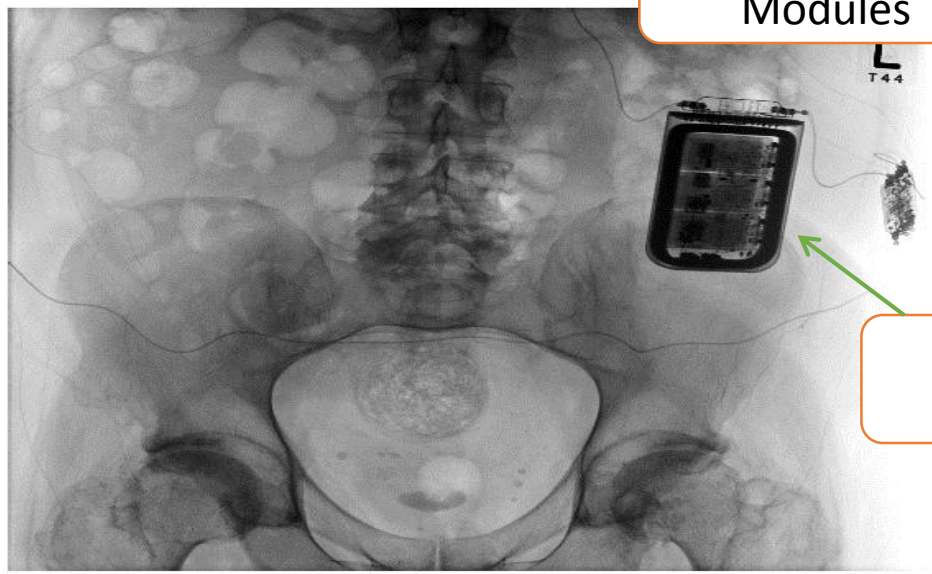


First human implant: Jan. 2016

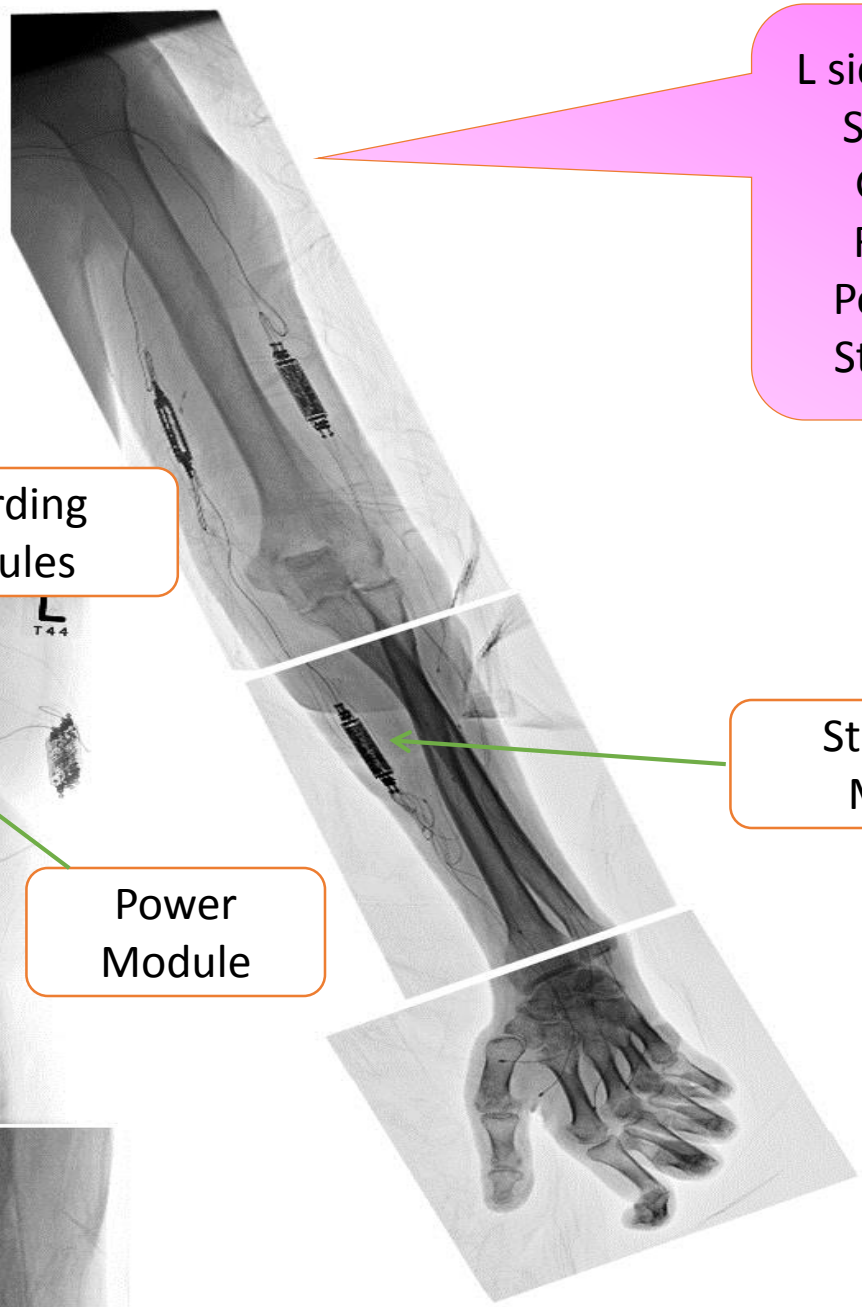


R side – 2nd Generation Grasp System

Recording Modules



Power Module



L side –NNP System Grasp Reach Postural Stability

Stimulating Modules

Regulatory Challenges to be especially aware of:

- Design controls
- Mechanical performance
- Biocompatibility
- EMC
- Sterilization

Guidance from Terry Hambrecht (circa ~1985):

"A prerequisite for designing an implanted system is having someone on your team who has done it before"

Summary

- Establish design principles early; adhere to them – good design trumps all else
- Be sure that design team has the correct expertise and experience
- Modularity has overwhelming benefits to incorporate
- Standardization (S) seems too early; Standardization (s) would enable different systems and system components to “talk together”. I suspect that this will be essential for regulatory considerations
- Regulatory challenges will be numerous. Have a team member who speaks the lingo.